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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/340,690	06/29/99	NI J	1488.0770007

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EXAMINER	
KEMMERER,E	
ART UNIT	PAPER NUMBER
1646	14

DATE MAILED: 06/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/340,690	NI et al.
Examiner	**Art Unit**
Elizabeth C. Kemmerer	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *30 Mar 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *27-38, 45-50, 57-62, and 81-86* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *27-38, 45-50, 57-62, and 81-86* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 9

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment filed 30 March 2001 (Paper No. 11) has been entered in full. Claims 1-26, 39-44, 51-56, 63-80 and 87-174 are canceled. Claims 27-38, 45-50, 57-62 and 81-86 are pending and under examination.

The Examiner location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Elizabeth C. Kemmerer, Group Art Unit 1646.

Withdrawn Objections And/Or Rejections

All previously made objections and/or rejections are *withdrawn* upon further consideration.

New Matter

The amendment filed 29 June 1999 (Paper No. 3) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the addition of Example 7.

Applicant is required to cancel the new matter in the reply to this Office action.

Applicant indicates in the amendment cited above that the information is "essentially the same" as specific portions of parent application PCT/US95/05058, which has been properly

incorporated by reference. However, this parent PCT application is in a foreign language, and no certified translation of the document could be found in the instant U.S. Application. Therefore, the official record does not show clear support for the added material, and a new matter objection is proper. Applicant is encouraged to provide a certified translation of PCT/US95/05058 so that the new matter issues can be resolved.

35 U.S.C. § 112, First Paragraph - New Matter

Claims 27-32 and 81-86 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite isolated polynucleotides comprising sequences that encode various portions of SEQ ID NO: 26. The record indicates that SEQ ID NO: 25 and 26 are originally disclosed in PCT/US95/05058, which is a parent of the instant application, the disclosure of which has been properly incorporated by reference. The subsequent sequence listings submitted in the instant applications which list SEQ ID NOS: 25 and 26 were not objected to as containing new matter, since the foreign language PCT application clearly had support for the sequences *per se*. However, the instant U.S. Application never discusses the molecules represented by SEQ ID NO: 25 or 26 and contains no written description of the inventions represented by the instant claims. For example, there is no discussion of isolated polynucleotides that *comprise* SEQ ID NO: 25, or vectors

comprising same, etc. Also, there is no description of the various fragments of SEQ ID NO: 25 and 26 recited in the claims. Although the parent PCT application PCT/US95/05058 my be relied upon to provide written description support for the invention claimed in the instant application (because the instant application properly incorporates the disclosure of PCT/US95/05058 by reference), the PCT application is in a foreign language, and no certified English translation can be found in the instant file. Therefore, it is not clear from the official record where the instantly claimed invention finds it written description. Applicant is encouraged to provide a certified translation of PCT/US95/05058, and to point to page and line number for the written description of the currently claimed invention.

35 U.S.C. §§ 101 and 112, First Paragraph - Utility

Claims 27-38, 45-50, 57-62 and 81-86 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

The claims are directed to isolated TNF receptor-like 2 (TR2) polypeptides corresponding to SEQ ID NO: 26, or encoded by cDNA clones deposited as ATCC Nos. 97059, 97058, or 97057. The specification never clearly asserts that the TR2 of SEQ ID NO: 26 or encoded by the deposited clones binds a TNF, or mediates any particular effect. The art acknowledges that the TNF receptors mediate diverse and even opposite effects (see specification's review of art at pp. 73-74). Therefore,

no specific biological activity has been established for the TR2 of SEQ ID NO: 26 or the deposited clones.

No well-established utility exists for newly isolated, complex biological molecules. However, the specification asserts the following as credible, specific and substantial patentable utilities for the claimed polypeptides:

1) screening for agonists/antagonists/modulators of TR2 or its ligands;

2) in diagnosing disease associated with TR2 or its ligands;

3) to treat TR2 associated diseases;

4) as a tissue marker;

5) to make antibodies to TR2; and

6) to isolate related polynucleotides.

Each of these shall be addressed in turn.

1) screening for agonists/antagonists/modulators of TR2 or its ligands. This asserted utility is credible, but not specific or substantial. Such screenings can be performed for any ligand-receptor pair. Furthermore, since the function of TR2 has not been established, significant further research would have to be performed before agonists/antagonists/modulators could be correctly identified. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) in diagnosing disease associated with TR2 or its ligands. This asserted utility is credible and specific, however, it is not substantial. The specification does not disclose any diseases

associated with altered levels or forms of the TR2 receptor or its ligands. Significant further experimentation would be required of the skilled artisan to identify individuals having such a disease. There is no disclosure, for example, of any symptoms associated with such a disease. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) to treat TR2 associated diseases. Similarly, this asserted utility is credible and specific, but it is not substantial. The specification does not disclose any conditions wherein there is a deficiency or over-abundance of TR2 or its ligands. Significant further experimentation would be required of the skilled artisan to identify individuals who suffer from a TR2 related disease, and then to determine a best course of treatment. There is no disclosure, for example, of whether the TR2 related polypeptides could be administered orally or parenterally, dosages, how to assay for improvement or intolerable levels of side effects, etc. Since this asserted utility is not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

4) as a tissue marker. This asserted utility is credible, but not specific or substantial. Tissue specificity can be determined, potentially, for any new polypeptide sequence. Although some data is given for tissue distribution of TR2, it is not clear if any of this information is relevant to the TR2 of SEQ ID NO: 26 or the deposited clones. Also, it is not clear that this is pertinent to claims reciting fragments or variants of SEQ ID NO: 26 or the deposited clones. It would appear that further experimentation would be required to determine the tissue specificity of TR2 of SEQ ID NO: 26 or the deposited clones.

5) to make antibodies to the polypeptides. This asserted utility is credible and substantial, but not specific. Antibodies can be made to any polypeptide. However, if the specification discloses nothing specific and substantial about the polypeptide, both the polypeptide and its antibodies have no patentable utility.

6) to isolate related polynucleotides. This asserted utility is credible, but not specific or substantial. Such could be done with any new polypeptide. Also, since nothing specific is disclosed about the specific polypeptides recited in the claims (SEQ ID NO: 26 or encoded by the deposited clones), further research would have to be performed to determine the significance of related polypeptides. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

Claims 27-38, 45-50, 57-62 and 81-86 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

No claims are allowed.

The art made of record and not relied upon is considered pertinent to applicant's disclosure. Montgomery et al., 1996, Cell 87:427-436. This paper discloses the structure and function of the receptor referred to in the instant application as TR2.

WO 97/04658, 13 Feb. 1997, Northwestern University. Similarly, this publication discloses the structure and function of the receptor referred to in the instant application as TR2.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

ECK
June 11, 2001